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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/556,900	04/12/2006	Palaniswamy Sunderraj	687-139	1726

23117 7590 03/31/2009

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EXAMINER	
FINN, MEGHAN R	

ART UNIT	PAPER NUMBER
1614	

MAIL DATE	DELIVERY MODE
03/31/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/556,900	SUNDERRAJ ET AL.	
	Examiner	Art Unit	
	MEGHAN FINN	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 January 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-32* is/are pending in the application.

4a) Of the above claim(s) *2-4,6-8,14-16 and 21-24* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 5, 9-13, 17-20, and 25-32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's Amendment filed January 08, 2009 has been received and entered into present application. No claims were canceled or added by applicant. Claims 2-4, 6-8, 14-16, and 21-24 remain withdrawn and thus claims 1, 6, 9-13, 17-20, and 25-32 are pending.

Applicants' arguments, filed January 08, 2009, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claim Rejections - 35 USC § 103 (new grounds of rejection)

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 5, 9-13, 17-20, 26-28, and 30-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Monti et al (Histamine H1 Receptor Antagonists in the Treatment of Insomnia, cited on applicant's IDS) in view of Leung et al. (WO 00/18365, cited on applicant's IDS), each already of record, for the reasons set forth at pages 6-8 of previous office action dated July 08, 2008, of which reasons are herein incorporated by reference.

Claims 1, 5, 9-13, 17-20, 26-28, and 30-31 were previously rejected under Monti et al., which teaches use of Triprolidine to treat insomnia, in view of Leung et al. which teaches edible films for fast release of pharmaceutical agents. Applicant has argued that Monti et al. teaches triprolidine as a treatment for daytime sleepiness and not as an aid in waking refreshed. The examiner finds this argument confusing as applicant has not pointed to where this treatment of daytime sleepiness is taught, and in the abstract Monti et al. teaches use of triprolidine to increase the likelihood of sleep and to treat insomnia (abstract). One of ordinary skill in the art would recognize that the inability to go to sleep would cause a lack of energy, and the ability to go to sleep would cause one with such difficulty to feel more refreshed upon waking than they would have without being able to go to sleep, or if that sleep had come with much more difficulty/time. Applicant further agues that triprolidine has not been approved as a sleep aid. However this is not required and the absence of such approval in no way suggests the novelty or unobviousness of the use as approval for use is a different distinction from patentability.

Applicant also argues that the general theme of Monti is that antihistamines should not be used as sleep aids. The examiner disagrees. In the section of the "conclusions" section pointed to by applicant, Monti concludes that such antihistamines are not supported for use of treating 1 week or longer insomnia. Monti et al. never says or implies that antihistamines cannot or should not be used for a one time treatment of insomnia, which the claims read upon. One of skill in the art would recognize that antihistamines are well known in the art for their sleep inducing properties, and Monti et al. explicitly states that they produce sleepiness or somnolence (abstract). One would be motivated to use this well known sleep inducing agent to treat insomnia, especially on a one time basis as antihistamines are well tolerated and safe.

Applicant's arguments were carefully considered but are not deemed persuasive and thus the rejection of claims 1, 5, 9-13, 17-20, 26-28, and 30-31 is **maintained.**

Claims 25, 29, and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Monti et al (Histamine H1 Receptor Antagonists in the Treatment of Insomnia, cited on applicant's IDS) in view of Leung et al. (WO 00/18365, cited on applicant's IDS) in further view of Hamilton et al. (A comparison of Triprolidine and cyclizine on histamine (H1) antagonism, subjective effects and performance tests in man, cited on applicant's IDS), each already of record, for the reasons set forth at pages 8-9 of previous office action dated July 08, 2008, of which reasons are herein incorporated by reference.

Claims 25, 29, and 32 were rejected over of Monti et al. in view of Leung et al., for the reasons discussed above, in further view of Hamilton et al. In claims 25, 29, and 32 applicant claims triprolidine hydrochloride. As discussed previously, Hamilton et al. teaches that triprolidine hydrochloride is the preferred form of triprolidine, and as applicant's arguments were solely directed towards the deficiencies of Monti et al, which have been addressed above, and thus for the reasons discussed above this argument is not deemed persuasive and thus the rejection of claims 25, 29, and 32 is **maintained.**

Conclusion

Rejection of claims 1, 5, 9-13, 17-20, 25-32 is deemed proper and is **maintained.**

No Claims of the present application are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Meghan Finn whose telephone number is (571) 270-3281. The examiner can normally be reached on 9:30am-7pm Mon-Thu, 9:30am-6pm Friday (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Meghan Finn

/Ardin Marschel/
Supervisory Patent Examiner, Art Unit 1614